

Notice of Allowability

Application No.

09/991,797

Examiner

Lisa V. Cook

Applicant(s)

JACKOWSKI ET AL.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to the response filed 8/15/05.
2. ☒ The allowed claim(s) is/are 1 and 39-46 (re numbered 1-9 respectively).
3. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) ☐ All b) ☐ Some* c) ☐ None of the:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
 5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
 - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
 - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
 - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. ☐ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3. ☐ Information Disclosure Statements (PTO-1449 or PTO/SB/08), Paper No./Mail Date _____
4. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material
5. ☐ Notice of Informal Patent Application (PTO-152)
6. ☒ Interview Summary (PTO-413), Paper No./Mail Date attached.
7. ☒ Examiner's Amendment/Comment
8. ☐ Examiner's Statement of Reasons for Allowance
9. ☐ Other _____

omdt
L/Cook
9/13/05

EXAMINER'S AMENDMENT

Amendment Entry

1. Applicants response to the Final Action mailed 6/2/05 is acknowledged (Paper filed 8/15/05). In the amendment filed therein, claims 39, 40, 42, and 44-46 were modified. Claims 2-38 have been canceled without prejudice or disclaimer. Currently claims 1 and 39-46 are pending and under consideration.

2. An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

3. Authorization for this examiner's amendment was given in a telephone interview with Ferris H. Lander (Reg. No. 43,377) on 9/13/05.

- I. In claim 1 line 2, delete [peptide].
- II. In claim 1 line 2, after "or" insert ----consisting of----
- III. In claim 1 lines 1 and 2, delete [diagnostic for Alzheimer's disease].
- IV. Replace claim 39 with the following:

A method for determining in a patient sample, the presence of an isolated biopolymer consisting of SEQ ID NO:1 or consisting of SEQ ID NO:2 which is linked to Alzheimer's disease comprising:

- (a) obtaining a sample from a patient;

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(b) conducting mass spectrometric analysis on said sample in a manner effective to maximize analysis of peptide fragments contained therein and comparing mass spectrum profiles of said isolated biopolymer marker consisting of SEQ ID NO:1 or consisting of SEQ ID NO:2 to mass spectrum profiles obtained and analyzed from said sample;

(c) confirming the presence of said isolated biopolymer marker consisting of SEQ ID NO:1 or consisting of SEQ ID NO:2 in said sample;

wherein the presence of said isolated biopolymer marker consisting of SEQ ID NO:1 or consisting of SEQ ID NO:2 is indicative of a link to Alzheimer's disease.

- V. In claim 44 line 1 replace "An Alzheimer's disease diagnostic kit" with ----A kit for determining the presence of an isolated biopolymer marker consisting of SEQ ID NO:1 or consisting of SEQ ID NO:2-----
- VI. In claim 44 line 3 after "or" insert ----consisting of----
- VII. In claim 45 delete [Alzheimer's disease diagnostic].
- VIII. In claim 46 delete [Alzheimer's disease diagnostic].

4. **NO EXTENSIONS OF TIME ARE PERMITTED TO FILE CORRECTED OR FORMAL DRAWINGS, OR A SUBSTITUTE OATH OR DECLARATION**, notwithstanding any indication to the contrary in the attached Notice of Allowability (PTO-37).

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If the following language appears on the attached Notice of Allowability, the portion lined through below is of no force and effect and is to be ignored¹:

A SHORTENED STATUTORY PERIOD FOR RESPONSE to comply with the requirements noted below is set to EXPIRE THREE MONTHS FROM THE "DATE MAILED" of this Office action. Failure to comply will result in ABANDONMENT of this application. ~~Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).~~

Similar language appearing in any attachments to the Notice of Allowability, such as in an Examiner's Amendment/Comment or in a Notice of Draftsperson's Patent Drawing Review, PTO-948, is also to be ignored.

5. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO fax center located in Crystal Mall 1. The faxing of such papers must conform to the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The Group 1641 Fax number is (571) 273-8300, which is able to receive transmissions 24 hours/day, 7 days/week.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lisa V. Cook whose telephone number is (571) 272-0816. The examiner can normally be reached on Monday - Friday from 7:00 AM - 4:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le, can be reached on (571) 272-0823.

Any inquiry of a general nature or relating to the status of this application should be directed to Group TC 1600 whose telephone number is (571) 272-1600.

¹ The language which is crossed out is contrary to amended 37 CFR 1.85(c) and 1.136. See "Changes to Implement the Patent Business Goals", 65 Fed. Reg. 54603, 54629, 54641, 54670, 54674 (September 8, 2000), 1238 Off. Gaz. Pat. Office 77, 99, 110, 135, 139 (September 19, 2000).

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR.

Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



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09/19/05